K113259

FEB 10 2012

V. 510(K) SUMMARY

510(k) SUMMARY

UE LifeSciences Inc.'s NoTouch BreastScan

UE LifeSciences, Inc.
4435 Lobella Court
Chester Springs PA 19425

Tel: 631-980-8340

Contact Person: Mihir Shah
Tel: 267-342-3303
Email: MShah@notouchbreastscan.com

Date Prepared: January 17, 2012

Common or Usual Name: NoTouch BreastScan

Classification Name: Class 1 per 21 CFR 884.2980 Telethermographic system.

Predicate Devices

BREASTSCAN IR

Intended Use / Indications for Use

The NoTouch BreastScan system is intended to be used as an adjunctive screening device for the detection of breast cancer by measuring various temperature parameters from the surface of the breast.

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive diagnostic screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

Technological Characteristics

The NoTouch BreastScan consists of a group of hardware and software components. The hardware components consist of:

- Two digital infrared cameras
- A computer system, with printer
- An air conditioner unit
- A specially designed mobile cart.

Software Components include:

- NoTouch BreastScan Software
- PDF Viewer
- Drivers for Infrared imagers
- ThermaCam Researcher Software

Performance Data

Testing of NoTouch BreastScan was performed as per the requirements. In all instances, the NoTouch BreastScan functioned as intended and the software and hardware performed as expected. Complete validation and verification was performed on all software and hardware subsystems.

Substantial Equivalence

The NoTouch BreastScan is as safe and effective as BreastScan IR. The NoTouch BreastScan has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the NoTouch BreastScan and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the NoTouch BreastScan is as safe and effective as BreastScan IR. Thus, the NoTouch BreastScan is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Mihir Shah
CEO
UE LifeSciences, Inc.
4435 Lobella Court
CHESTER SPRINGS PA 19425

FEB 10 2012

Re: K113259
Trade/Device Name: NoTouch BreastScan™ System
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic system
Regulatory Class: I
Product Code: LHQ
Dated: January 17, 2012
Received: January 23, 2012

Dear Mr. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

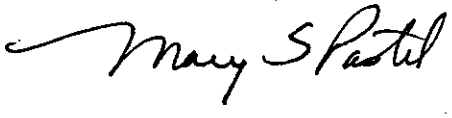
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

IV. INDICATIONS FOR USE STATEMENT

Indications for Use Statement

510(k) Number (if known): K113259

Device Name: NoTouch BreastScan™ System

Indications for Use:

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult.

The device is for adjunctive diagnostic screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K113259